## FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

# Peripheral and Central Nervous System Advisory Committee (PCNS) Meeting

Sheraton Silver Spring Hotel, Cypress Ballroom 8777 Georgia Avenue, Silver Spring, Maryland November 13, 2013

#### MEETING ROSTER

## **DESIGNATED FEDERAL OFFICER (Non-Voting)**

# Glendolynn S. Johnson, PharmD

Division of Advisory Committee & Consultant Management Office of Executive Programs, CDER, FDA

# PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

# Emilia Bagiella, PhD

Professor of Biostatistics
Department of Health Evidence and Policy
Mount Sinai School of Medicine
New York, New York

## Robert R. Clancy, MD

Professor of Neurology and Pediatrics
The University of Pennsylvania School of
Medicine
Division of Neurology
The Children's Hospital of Philadelphia
Philadelphia, Pennsylvania

# Nathan B. Fountain, MD

(Chairperson)
Professor, Department of Neurology
Director, FE Dreifuss Comprehensive Epilepsy
Program
University of Virginia School of Medicine
Charlottesville, Virginia

# Richard P. Hoffmann, PharmD

(Consumer Representative) Hernando, Florida

# Michelle M. Mielke, PhD

Associate Professor Division of Epidemiology Department of Health Sciences Research Mayo Clinic Rochester, Minnesota

## Paul B. Rosenberg, MD

Associate Professor of Psychiatry and Behavioral Sciences
Division of Geriatric Psychiatry and
Neuropsychiatry
John Hopkins University School of Medicine
Baltimore, Maryland

# Justin A. Zivin, MD

Professor Emeritus University of California San Diego La Jolla, California

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# **MEETING ROSTER (cont.)**

# PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

## Lynn Kramer, MD, FAAN

(Industry Representative)
President, Neuroscience PCU
Eisai, Inc.
Wood Cliff Lake, New Jersey

## **TEMPORARY MEMBERS (Voting)**

# G. Caleb Alexander, MD, MS

Associate Professor of Epidemiology and Medicine Co-Director of the Johns Hopkins Center for Drug Safety and Effectiveness Johns Hopkins Bloomberg School of Public Health

# Joao Ascensao, MD, PhD, FACP

Baltimore, Maryland

Acting Chief, Hematology Chair, R&D Committee VA Medical Center Professor, Departments of Medicine and Immunology George Washington University School of Medicine Washington, District of Columbia

# David E. Blumenthal, MD

Assistant Professor of Medicine Division of Rheumatology Case Western Reserve University School of Medicine Louis Stokes Cleveland VA Medical Center Cleveland, Ohio

# David K. Klassen, MD

Professor of Medicine Division of Nephrology Department of Medicine University of Maryland School of Medicine Baltimore, Maryland

# Richard J. Kryscio, PhD

Professor, Statistics and Biostatistics University of Kentucky Lexington, Kentucky

## Ying Lu, PhD

Professor of Biostatistics
Department of Health Research and Policy
Stanford University School of Medicine Director,
Director, Palo Alto Cooperative Studies Program
Coordinating Center, VA Palo Alto Health Care
System
Mountain View, California

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# **MEETING ROSTER (cont.)**

# **TEMPORARY MEMBERS (Voting)**

# **Cynthia Sitcov**

(Patient Representative) Arlington, Virginia

## Roy E. Smith, MD

Professor of Medicine Division of Hematology-Oncology University of Pittsburgh Medical Center Pittsburgh, Pennsylvania

## T. Mark Woods, PharmD

Clinical Coordinator and Residency Program Director,Pharmacy Department Saint Luke's Hospital Kansas City, Missouri

## E. Ann Yeh, MD, FRCPC

Associate Professor of Pediatrics (Neurology)
University of Toronto
Director, Child Neurology Training Program
Director, Pediatrics MS and Demyelinating Disorders
Program
Associate Scientist, Research Institute
Hospital for Sick Children

## Mitchell T. Wallin, MD, MPH

Clinical Associate Director, Veterans Affairs Multiple Sclerosis Center of Excellence-East Associate Professor of Neurology, Georgetown University & University of Maryland School of Medicine Washington, District of Columbia

# FDA PARTICIPANTS (Non-Voting)

## Ellis Unger, MD

Director, Office of Drug Evaluation I (ODE-I) Office of New Drugs (OND), CDER, FDA

# Eric Bastings, MD

Toronto, Canada

Acting Director Division of Neurology Products (DNP) ODE-I, OND, CDER, FDA

## Billy Dunn, MD

Acting Deputy Director, DNP ODE-I, OND, CDER, FDA

# John Marler, MD

Clinical Reviewer, DNP ODE-I, OND CDER, FDA

# Evelyn Mentari, MD, MS

Safety Reviewer, DNP ODE-I, OND, CDER, FDA